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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,091	12/16/2004	Giancarlo Cravotto	48239	5511
1609	7590	04/10/2007	EXAMINER	
ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P. 1300 19TH STREET, N.W. SUITE 600 WASHINGTON,, DC 20036			CARR, DEBORAH D	
			ART UNIT	PAPER NUMBER
			1621	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	04/10/2007		PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/518,091	CRAVOTTO, GIANCARLO	
	Examiner Deborah D. Carr	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 January 2007.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 13-19 is/are allowed.  
 6) Claim(s) 1-12 20-24 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 10 January 2007 regarding claims 1-12, 20-23 rejected under 35 USC§112 1<sup>st</sup> paragraph have been fully considered but they are not persuasive.
2. Applicant's arguments, see page 9-10, filed 10 January 2007, with respect to claims 1, 9-16 & 19 have been fully considered and are persuasive. The rejection of claims 1, 9-16 & 19 under 35 USC 102(b) has been withdrawn.
3. Applicant's arguments see page 8-9, filed 10 January 2007, with respect to claims 9-12, 16-18 & 20 have been fully considered and are persuasive. The rejection of claims 9-12 under 35 USC§112 2<sup>nd</sup> paragraph has been withdrawn.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-12, 20-24 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. Claims 2-3 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diabetic peripheral neuropathy, does not reasonably provide enablement for all peripheral neuropathies or vascular diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Peripheral neuropathies or vascular diseases can be caused by various reasons such as hereditary disorders, systemic or metabolic disorders, infectious or inflammatory conditions, and exposure to toxic compounds, drugs or miscellaneous causes. Applicant's disclosure does not provide enablement for all of the cause for these two diseases..

**Applicants' argue the following:**

Applicants respectfully disagree.

As noted in the previous response, independent claims 1 and 2 are directed to a method of preparation of a pharmaceutically or nutraceutically effective composition. Thus, the claims are directed to methods of producing the composition and are not directed to a method of treatment. The specification and the Examples are enabling to one of ordinary skill in the art to produce a pharmaceutically or nutraceutically effective composition from a carrier or vehicle and a compound as recited in claim 1. The claims are not directed to a method of treatment so that examples of the efficacy of the composition for each treatment are not needed.

In view of the above, the claims are enabled by the specification.

Applicants continue to argue the claims are drawn to the preparation of pharmaceutically or nutraceutically effective compositions therefore the specification is not required to produce examples directed to the treatment or prevention of a clinical condition using the compositions.

As stated previously, the specification specifically pages 1-7 recite that these compounds are novel in the use of therapeutic, cosmetic and nutraceutical field of alcohols, acids and esters of those acids having long mono- or poly-unsaturated hydrocarbon chain. Based on this disclosure, one would need to enable the treatment or prevention of the clinical conditions recited using the instant compounds contained in the instant compositions.

There aren't any examples drawn to the treatment or prevention of a clinical condition for which the pharmaceutically or nutraceutically effective compositions are indicated and there is not seen sufficient correlative data to substantiate the preventive efficacy of any of the pharmaceutically or nutraceutically effective compositions set forth in the instant disclosure.

*Conclusion*

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee

pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Allowable Subject Matter***

8. Claims 13-19 allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah D. Carr whose telephone number is 571-272-0637.

The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or

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access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or  
571-272-1000.



Deborah D. Carr  
DEBORAH D. CARR  
PRIMARY EXAMINER

ddc